

Amendment

Application N . 09/689139
Page 2

invention was made to employ the compositions of Fritz to make the catheters of Wang in order to make them heat sterilizable.

Applicants traverse the rejection.

The claims of the present invention are directed to balloon catheters.

The Examiner is relying on steam sterilization and transparency as the motivating factor in combining Wang et al. and Fritz et al. However, such properties would not provide motivation to employ such material in the formation of balloon catheters. Applicants argued in the Response to the last Office Action, and maintain the argument that forming a balloon and subsequently steam sterilizing is a process which is not followed by a person skilled in the balloon forming art. See the enclosed declaration under 37 C.F.R. §1.132 by Paul Miller who has extensive experience in the balloon catheter art in support of this argument.

Fritz et al. describe steam sterilization at 134° C (col. 2, lines 27-31 and col. 7, lines 10-14) for medical instruments such as catheters, tubes, tracheal tubes and the like. There is no suggestion by Fritz et al. to employ such materials in balloons. Balloons, in contrast to catheters and tracheal tubes, are very thin walled, much more delicate structures, and is thus, not a medical instrument as defined in Fritz et al. Applicants submit that balloons are not steam sterilized because of the shrinkage that results from subjecting them to the heat required for steam sterilization. This is supported by the declaration of Paul Miller. Balloon catheters are sterilized with ethylene oxide gas at a temperature of 45° C to 50° C, temperatures which are significantly different lower than 134° C. See Wang et al., US 5348538 (col. 11, lines 55-59).

Wang et al. do describe an annealing process in which the dimensions of the catheter balloon are decreased. However, this is the last step in the balloon formation process, and is conducted at temperatures of 25° C to 100° C and preferably 65° C to 80° C which are also significantly lower than 134° C. Once the catheter balloons have been completely formed, however, the temperatures to which they are subjected are much lower at 45° C to 50° C as described above. Thus, there is nothing in Wang et al. that would provide a motivation or suggestion to steam sterilize under the conditions described by Fritz et al.

Furthermore, there is nothing in Fritz et al. to suggest that the materials described therein would have the properties required to successfully make a balloon catheter which would have properties acceptable in the art for catheter balloon performance.

Amendment

Application N . 09/689139
Page 3

In fact, the properties discussed in Wang et al. include *minimum burst pressure*, which is the point during inflation at which the balloon will burst, and *expansion or stretching characteristics* which is a measure of how much the diameter of the balloon changes during inflation and is a factor of both the wall thickness and the material from which the balloon is made. See col. 1, lines 37-62. Fritz et al. do not discuss such properties, and in fact make no suggestion that such materials would have the expansion or stretching characteristics required for balloons. This is also supported by the declaration of Paul Miller.

Consequently, there is no motivation to combine the materials described by Fritz et al. in the balloon catheters of Wang et al. as required to support a case of obvious under 35 U.S.C. §103(a). There must be some suggestion or motivation for an ordinary person of skill in the art to combine the references. As there is no motivation to combine these references, Applicants submit that a rejection under 35 U.S.C. §103(a) is not supported. Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-4, 8-13 and 15-17 under 35 U.S.C. §103(a) as obvious over Fritz et al. in view of Wang et al.

Claims 5-7, 14 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wang in view of Schmid. The Office Action asserts that it would have been obvious to employ the polyamide- and silane-containing compositions of Schmid in the production of the catheters of Wang in order to give the Wang catheters better mechanical properties.

Applicants traverse the rejection.

Schmid describes a process for the preparation of crosslinked shapes. At col. 1, lines 24-41, Schmid states that the performance profiles of new types of polyamides do not yet satisfy all the requirements, especially for construction elements, tools, wear-resistant shaped articles such as cable sheaths, or materials with very high creep resistance and toughness and it is among the objects of the invention to provide polyamide shaped articles with more highly improved mechanical properties. The Office Action directs us to col. 4, lines 35+, stating that this is motivation to employ these compositions in the balloon catheters of Wang et al. We disagree.

At col. 4, lines 35+, Schmid refers to the importance of the properties of yield strength, creep under load and heat, swelling due to solvents, and resistance to dripping of molten

Amendment

Application No. 09/689139

Page 4

polymer under the action of heat and fire on the polyimide shaped articles described therein.

Wang et al., however, describe none of these properties in relation to the formation of the balloon catheters therein. Rather, Wang et al. describe at col. 1, lines 37-62, that consideration is given to the *minimum burst pressure*, which is the point during inflation at which the balloon will burst, and *expansion or stretching characteristics* which is a measure of how much the diameter of the balloon changes during inflation and is a factor of both the wall thickness and the material from which the balloon is made. See col. 1, lines 37-62. Schmid is silent as to these properties.

There is no indication that the materials described in Schmid would have the proper minimum burst pressure or proper expansion characteristics that would make them useful as balloon materials, and there is nothing in Schmid to indicate that the materials described therein could be successfully employed in the balloon catheters of Wang et al. Consequently, Applicants submit that Wang et al. provides no motivation or suggestion to employ the compositions of Schmid, in the balloon catheters described therein. Based on the foregoing arguments, Applicants respectfully request that the rejection of claims 5-7, 14 and 18 under 35 U.S.C. §103(a) as being obvious over Wang et al. in view of Schmid.

Amendment

Application No. 09/689139
Page 5

CONCLUSION

Claims 1-19 are pending in the Application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing arguments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: March 24, 2003

By: 

Lisa R. Lindquist

Registration No.: 43071

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
LRL/tas
(\\wpwork\lrl\09178us_and_20030318.doc

FAX RECEIVED
MAR 25 2003
GROUP 1700